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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,809	10/30/2006	Daniel Carter	P07895US02/BAS	8256

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
11/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,809	CARTER ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *8-13,17-21 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14-16 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed July 13, 2009 has been received and entered. Claims 1-25 remain pending in the instant application, of which claims 8-13, 17-21 and 25 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Objections

1. The objection of claim 5 for failing to end with the punctuation mark of a "period" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The rejection of claims 1-7, 14-16 and 22-24 under 35 U.S.C. 102(e) as being anticipated by Yu et al is maintained.

Applicants are asserting that Yu et al relates to well known fusion proteins using the regular human serum albumin protein, and not fragments or polymers of albumin as in the presently claimed invention. Applicants further assert that Yu does not disclose or suggest using a fusion protein to optimize the half-life of a therapeutic polypeptide.

Applicants arguments have been fully considered, but are not found to be persuasive.

First, Applicants assert that Yu only teaches regular human serum albumin, not fragments or polymers as presently claimed. However, Applicants are respectfully directed back to their own claim language which recites "***comprising*** a fragment of human serum albumin containing at least one domain or subdomain..." The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any,are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or" characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112

F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Accordingly, Applicants cannot claim a polypeptide comprising a fragment of human serum albumin and expect the full length albumin molecule to be excluded from the breadth of the claim. (See MPEP 2111.02).

Finally, Applicants assert that Yu does not disclose or suggest using a fusion protein to optimize the half-life of a therapeutic polypeptide. However, Yu disclose of therapeutically active polypeptides fused to human serum albumin. This is structurally identical to the requirements of Applicants instantly filed claims, accordingly any property of having an optimized half-life is an inherent result of the molecule being structurally identical to the requirements set forth in the instantly filed claims.

Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The claims are directed to a fusion polypeptide comprising a fragment of human serum albumin containing at least one domain or subdomain or combinations thereof and a therapeutically active polypeptide attached thereto in such a manner wherein the human serum albumin fragment optimizes the half-life of said therapeutically active polypeptide in the bloodstream depending on the molecular weight of the fragment.

Yu et al (US Patent Number 7,244,833) disclose of recombinant polypeptides comprising a therapeutically active polypeptide fused to human serum albumin in such a manner to increase the plasma half life of the fusion protein. (See abstract, summary and claims).

Accordingly, Yu et al disclose of each and every limitation set forth in the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1-7, 14-16 and 22-24 under 35 U.S.C. 102(b) as being anticipated by Rosen et al is maintained.

Applicants arguments are the same as those set forth above in rejection number 2, and have been fully addressed above in rejection number 2.

The claims are directed to a fusion polypeptide comprising a fragment of human serum albumin containing at least one domain or subdomain or combinations thereof and a therapeutically active polypeptide attached thereto in such a manner wherein the

human serum albumin fragment optimizes the half-life of said therapeutically active polypeptide in the bloodstream depending on the molecular weight of the fragment.

Rosen et al (WO 2001/079442) disclose of recombinant polypeptides comprising a therapeutically active polypeptide fused to human serum albumin in such a manner to increase the plasma half life of the fusion protein. (See abstract, summary and claims).

Accordingly, Rosen et al disclose of each and every limitation set forth in the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 22-24 under 35 U.S.C. 102(b) as being anticipated by Nissen et al is maintained.

Applicants are asserting that Nissen does not suggest the use of a human serum albumin polymer in optimizing the half-life of a therapeutic protein as in the present claims. Applicants assert that in other words the reference is not disclosing a polymer of human serum albumin, it is saying that the human serum albumin is considered a polymer only because it is made up of a chain of amino acid monomers.

Applicants arguments have been fully considered, but are not found to be fully persuasive.

Applicants assert that Nissen does not suggest the use of a human serum albumin polymer in optimizing the half-life of a therapeutic protein as in the present claims. Applicants further assert that the reference is not disclosing a polymer of

human serum albumin, it is saying that the human serum albumin is considered a polymer only because it is made up of a chain of amino acid monomers. However, Applicants are again directed back to the teachings of Nissen. Nissen disclose of therapeutically active polypeptides fused to human serum albumin. (See paragraph number 3, 24 and 124). This is structurally identical to the requirements set forth in the instant claims. Accordingly, any property any property of having an optimized half-life is an inherent result of the molecule being structurally identical to the requirements set forth in the instantly filed claims. Furthermore, Applicants own arguments acknowledge that human serum albumin can be considered a "polymer" as taught by Nissen. This is precisely what is required by the instant claims, a polymer of human serum albumin, again, structurally identical to the requirements set forth in the rejected claims.

Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The claims are directed to a fusion polypeptide comprising a polymer of human serum albumin and a therapeutically active polypeptide attached thereto in such a manner wherein the human serum albumin polymer optimizes the half-life of said therapeutically active polypeptide in the bloodstream depending on the molecular weight of the polymer.

Nissen et al (US Publication 2002/0004483) disclose of recombinant polypeptides comprising a therapeutically active polypeptide (granulocyte colony stimulating factor molecules) fused to a polymer of human serum albumin in such a manner to increase the plasma half life of the fusion protein. (See paragraph number 3, 24 and 124).

Accordingly, Nissen et al disclose of each and every limitation set forth in the instantly filed claims.

For reasons of record as well as the reasons set forth above this rejection is maintained for reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
November 3, 2009